DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 01N–0191]

Medical Devices; Global Harmonization Task Force; Study Group 1; Working Draft "Medical Devices Classification;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft document entitled "Medical Devices Classification." Study Group 1 of the Global Harmonization Task Force (GHTF) has prepared this document on premarket regulation of medical devices. This document is intended to provide information only and represents a harmonized proposal that may be used by governments developing or updating their premarket regulation schemes for medical devices. This draft document is not being issued as an FDA guidance. Elements of the approach set forth in this document may not be consistent with current U.S. regulatory requirements. However, FDA is publishing the draft at this time to give the public an opportunity to comment on the document before the agency resumes discussions with other countries. Public comments will help FDA decide whether and how the agency can adapt these recommendations to our own regulatory requirements.

DATES: Submit written comments concerning this at any time. FDA must submit its comments on this draft to GHTF by July 1, 2001. FDA will consider any comments that it receives after it prepares its comments for GHTF in future discussions with GHTF on this issue.

ADDRESSES: Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the

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document. Submit written requests for single copies on a 3.5″ diskette of the draft document entitled "Medical Devices Classification" to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. The GHTF was established in 1992 to facilitate medical device harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world. The most recent GHTF meeting was held in September 2000, in Ottawa, Canada. The GHTF is a voluntary consortium of representatives from medical device regulatory authorities and trade associations from around the world, including Canada, Japan, and the European Union.

The objective of the GHTF is to encourage harmonization of regulatory systems for medical devices in order to facilitate trade while recognizing the right of participating members to enforce regulatory requirements considered most suitable to protect the public health of their citizens. One of the ways this objective is achieved is by identifying and developing areas of international cooperation that can reduce differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF has formed four study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by Study Group 1.

Study Group 1 was formed in January 1993, and was originally tasked with identifying differences between various premarket regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and offer guidance that could help lead to harmonization. As a result of their efforts, this group has developed the document entitled "Medical Devices Classification." This GHTF document suggests some general guidelines for classification of medical devices to encourage harmonization. It recommends that there is a need to classify medical devices based on their risk to patients, users, and other persons; and that there is a benefit for manufacturers and regulatory authorities if a globally harmonized classification system is developed. The classification framework presumes that the risk presented by a particular device depends on its intended purpose and the effectiveness of the risk management techniques applied during the design, manufacture, and use of that device. The document also suggests that the regulatory controls applied should be proportional to the level of risk associated with a medical device and should increase with the associated degree of risk presented by the medical device. The GHTF document suggests four global classifications of devices.

This document also presents a decision tree logic that may help regulatory authorities develop different parameters that might be used to classify specific devices.

When FDA discusses draft documents with representatives of other countries, we seek public comment on the resulting documents. We believe that it is important to publish draft documents for comment at the same time as other countries so we may review the public comments and resume discussions in a timely manner. Because other countries do not follow our good guidance practices (GGPs), we do not require draft documents that result from international discussions to comply with the format requirements of our GGP regulation. The GGP regulation does require that any final FDA guidance that results from international discussions will comply with the GGP regulation.

II. Electronic Access

In order to receive "Medical Devices Classification" via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1327) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft document may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

III. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. FDA must submit its written comments to the GHTF by July 1, 2001. FDA will consider any comments that it receives in a timely manner, while preparing those comments. FDA will consider any public comments that it receives after preparation of its comments to GHTF in future discussions on this issue. Submit two copies of any comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/7/01

May 7, 2001.

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Linda S. Kahan

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